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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

HANS MATHISEN, Derivatively on Behalf of TREVENA, INC., Plaintiff, v. MAXINE GOWEN, CARRIE L. BOURDOW, JONATHAN VIOLIN, LEON O. MOULDER, MICHAEL R. DOUGHERTY, BARBARA YANNI, JULIE H. MCHUGH, JAKE R. NUNN, ANNE M. PHILLIPS, ROBERTO CUCA, DAVID SOERGEL, and ADAM M. KOPPEL, Defendants, -and- TREVENA, INC., a Delaware corporation, Nominal Defendant.	Case No. 18-5482 **VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT FOR BREACH OF FIDUCIARY DUTY, WASTE OF CORPORATE ASSETS, AND UNJUST ENRICHMENT** **DEMAND FOR JURY TRIAL**

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Plaintiff, by his attorneys, submits this Verified Stockholder Derivative Complaint for Breach of Fiduciary Duty, Waste of Corporate Assets, and Unjust Enrichment. Plaintiff alleges the following on information and belief, except as to the allegations specifically pertaining to plaintiff which are based on personal knowledge. This complaint is also based on the investigation of plaintiff's counsel, which included, among other things, a review of public filings with the U.S. Securities and Exchange Commission ("SEC") and a review of news reports, press releases, and other publicly available sources.

NATURE AND SUMMARY OF THE ACTION

1. This is a stockholder derivative action brought by plaintiff on behalf of nominal defendant Trevena, Inc. ("Trevena" or the "Company") against certain of its officers and directors for breaches of fiduciary duties and violations of law. These wrongs resulted in hundreds of millions of dollars in damages to Trevena's reputation, goodwill, and standing in the

business community. Moreover, these actions have exposed Trevena to hundreds of millions of dollars in potential liability for violations of state and federal law.

2. Trevena is a drug development company that has yet to have a product reach market. In order to be sold in the United States, a drug first has to be approved for sale by the Food and Drug Administration ("FDA"). The Company's most advanced drug candidate during the relevant period was its oliceridine injection, which Trevena planned to give the tradename "Olinvo". Olinvo was meant to treat patients' moderate to severe acute pain in the hospital or similar setting. In order to show that Olinvo is both safe and effective, and therefore should receive FDA approval, Trevena had to conduct a series of test or trials on the drug. The trials take place is a series of "phases," with each phase more extensive and therefore more expensive. Phase III is the last trial that a company undertakes before submitting a new drug application ("NDA") to the FDA for approval of the drug.

3. This action arises out of the Individual Defendants' (as defined herein) disregard for their fiduciary duties by pushing forward with a phase III clinical study for Olinvo, despite repeated meetings with the FDA questioning the study's methodology and endpoints. The Company's meetings with the FDA were not public and therefore investors did not know about the complaints regarding the phase III trial. Instead, based on the Defendants' improper statements detailed below, the public believed that Olinvo was poised to become a breakthrough drug that worked as well or better than morphine (its primary competitor) with less adverse side effects.

4. The truth was that Olinvo neither worked as well as morphine, nor showed statistically significant reduction in side effects. Moreover, the FDA, when recommending the rejection of approval of Olinvo revealed that it had significant questions concerning Trevena's

phase III drug trial format, including that it "did not agree with the proposed dosing in the Phase 3 studies," the proposed primary endpoint, or the "Propose non-inferiority margin for comparing morphine to olicderidine."

5. In the wake of this disclosure, Trevena's stock plunged more than 80%, nearly $7 per share from its relevant period high, to close at just $1.07 per share on October 9, 2018, erasing almost $338 million in market capitalization.

6. On October 11, 2018, the Company revealed that the FDA officially denied its NDA for Olinvo. On this news, the Trevena's stock price fell to under $1 per share. The Company's stock price continued to fall and now trades at just $0.61 per share, calling into question Trevena's continued listing on the Nasdaq stock exchange.

7. Further, as a direct result of this unlawful course of conduct, Trevena is now the subject of numerous federal securities class action lawsuits filed in the U.S. District Court for the Eastern District of Pennsylvania on behalf of investors who purchased Trevena's shares at inflated prices (the "Securities Class Actions").

8. Plaintiff brings this action against the Individual Defendants to repair the harm that they caused with their faithless actions.

JURISDICTION AND VENUE

9. Jurisdiction is conferred by 28 U.S.C. §1332. Complete diversity among the parties exists and the amount in controversy exceeds $75,000, exclusive of interests and costs.

10. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this District, or is an individual who has sufficient minimum contacts with this District to render the

exercise of jurisdiction by the District courts permissible under traditional notions of fair play and substantial justice.

11. Venue is proper in this Court in accordance with 28 U.S.C. §1391(a) because: (i) Trevena maintains its principal place of business in this District; (ii) one or more of the defendants either resides in or maintains executive offices in this District; (iii) a substantial portion of the transactions and wrongs complained of herein, including the defendants' primary participation in the wrongful acts detailed herein, and aiding and abetting and conspiracy in violation of fiduciary duties owed to Trevena, occurred in this District; and (iv) defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

THE PARTIES

PLAINTIFF

12. Plaintiff Hans Mathisen was a stockholder of Trevena at the time of the wrongdoing complained of, has continuously been a stockholder since that time, and is a current Trevena stockholder. Plaintiff is a citizen of Canada.

NOMINAL DEFENDANT

13. Nominal Defendant Trevena is a Delaware corporation with principal executive offices located at 955 Chesterbrook Boulevard, Suite 110, Chesterbrook, Pennsylvania. Accordingly, Trevena is a citizen of Delaware and Pennsylvania. Trevena was incorporated in Delaware as Parallax Therapeutics, Inc. in November 2007 and changed its name to Trevena, Inc. in January 2008. Trevena is a biopharmaceutical company focused on the development and commercialization of new and innovative treatment options for patients in pain. The Company operates in one segment, with its leading drug candidate being oliceridine. Trevena received

notice from the FDA on November 2, 2018 that its NDA for oliceridine was rejected, requiring additional clinical data. The Company has not turned a profit and has had a negative cash flow since its inception.

DEFENDANTS

14. Defendant Maxine Gowen ("Gowen") is a Trevena director and has been since November 2007. Defendant Gowen was previously Trevena's President and Chief Executive Officer ("CEO") from November 2007 to October 2018. Defendant Gowen founded Trevena in 2007. Defendant Gowen is named in the related Securities Class Actions complaints that allege she violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). Defendant Gowen knowingly or recklessly made improper statements concerning Olinvo's Phase III and the Company's dealings with the FDA. Trevena paid defendant Gowen the following compensation as a director:

Year	Salary	Option Awards	Non-Equity Incentive Plan Compensation	All Other Compensation	Total
2017	$536,667	$1,992,612	$268,785	$10,800	$2,808,864
2016	$513,917	$1,917,756	$260,000	$10,600	$2,702,273

Defendant Gowen is a citizen of Pennsylvania.

15. Defendant Carrie L. Bourdow ("Bourdow") is Trevena's President, CEO and a Director and has been since October 2018, and was Trevena's Executive Vice President and Chief Operating Officer from January 2018 to October 2018. Defendant Bourdow was also Trevena's Senior Vice President and Chief Commercial Officer from May 2015 to January 2018. Defendant Bourdow is named in the related Securities Class Actions complaints that allege she violated Sections 10(b) and 20(a) of the Exchange Act. Defendant Bourdow knowingly, recklessly, or with gross negligence made improper statements concerning Olinvo's Phase III

and the Company's dealings with the FDA. Trevena paid defendant Bourdow the following compensation as an executive:

Year	Salary	Option Awards	Non-Equity Incentive Plan Compensation	All Other Compensation	Total
2017	$341,169	$606,868	$130,413	$10,800	$1,089,250
2016	$330,417	$520,534	$116,025	$10,600	$977,576

Defendant Bourdow is a citizen of Pennsylvania.

16. Defendant Jonathan Violin ("Violin") is Trevena's Senior Vice President, Scientific Affairs & Investor Relations Officer and has been since January 2018. Defendant Violin was also Trevena's Vice President, Corporate Strategy & Investor Relations from April 2017 to January 2018; Senior Director of Investor Relations from January 2016 to April 2017; and Director of Investor Relations from April 2014 to January 2016. Defendant Violin is named in the related Securities Class Actions complaints that allege he violated Sections 10(b) and 20(a) of the Exchange Act. Defendant Violin knowingly or recklessly made improper statements concerning Olinvo's Phase III and the Company's dealings with the FDA. Defendant Violin is a citizen of Pennsylvania.

17. Defendant Leon O. Moulder ("Moulder") is Trevena's Chairman of the Board and has been since June 2013 and a director and has been since November 2011. Defendant Moulder knowingly or recklessly made improper statements in the Company's press releases and public filing concerning Olinvo's Phase III and the Company's dealings with the FDA. Defendant Moulder is a citizen of Florida.

18. Defendant Michael R. Dougherty ("Dougherty") is a Trevena director and has been since August 2013. Defendant Dougherty is also Chairman of the Audit Committee and has been since at least April 2016. Defendant Dougherty knowingly or recklessly made improper

statements concerning Olinvo's Phase III and the Company's dealings with the FDA. Defendant Dougherty is a citizen of Pennsylvania.

19. Defendant Barbara Yanni ("Yanni") is a Trevena director and has been since July 2014. Yanni is also a member of the Audit Committee and has been since at least April 2016. Yanni knowingly or recklessly made improper statements concerning Olinvo's Phase III and the Company's dealings with the FDA. Defendant Yanni is a citizen of New Jersey.

20. Defendant Julie H. McHugh ("McHugh") is a Trevena director and has been since July 2014. Defendant McHugh knowingly or recklessly made improper statements concerning Olinvo's Phase III and the Company's dealings with the FDA. Defendant McHugh is a citizen of Pennsylvania.

21. Defendant Jake R. Nunn ("Nunn") is a Trevena director and has been since July 2013. Defendant Nunn knowingly or recklessly made improper statements concerning Olinvo's Phase III and the Company's dealings with the FDA. Defendant Nunn is a citizen of California.

22. Defendant Anne M. Phillips ("Phillips") is a Trevena director and has been since December 2014. Defendant Phillips knowingly or recklessly made improper statements concerning Olinvo's Phase III and the Company's dealings with the FDA. Defendant Phillips is a citizen of Pennsylvania.

23. Defendant Roberto Cuca ("Cuca") was Trevena's Senior Vice President and Chief Financial Officer from September 2013 to May 2018. Cuca is named in the related Securities Class Actions complaints that allege he violated Sections 10(b) and 20(a) of the Exchange Act. Defendant Cuca knowingly, recklessly, or with gross negligence made improper statements concerning Olinvo's Phase III and the Company's dealings with the FDA. Defendant Cuca is a citizen of Pennsylvania.

24. Defendant David Soergel ("Soergel") was Trevena's Chief Medical Officer from March 2015 to August 2017 and Senior Vice President, Clinical Development from September 2012 to February 2015. Soergel is named in the related Securities Class Actions complaints that allege he violated Sections 10(b) and 20(a) of the Exchange Act. Defendant Soergel knowingly, recklessly, or with gross negligence made improper statements concerning Olinvo's Phase III and the Company's dealings with the FDA. Trevena paid defendant Soergel the following compensation as a director:

Year	Salary	Option Awards	Non-Equity Incentive Plan Compensation	All Other Compensation	Total Disclosed
2017	N/A	N/A	$71,812	N/A	$71,812
2016	N/A	N/A	N/A	N/A	N/A

Defendant Soergel is a citizen of Pennsylvania.

25. Defendant Adam M. Koppel ("Koppel") was a Trevena director from September 2014 to October 2018. Defendant Koppel was also a member of the Audit Committee from at least April 2016 to his resignation in October 2018. Defendant Koppel knowingly or recklessly made improper statements concerning Olinvo's Phase III and the Company's dealings with the FDA. Defendant Koppel is a citizen of Massachusetts.

26. The defendants identified in ¶¶14-15 are referred to herein as the "Officer Defendants." The defendants identified in ¶¶16-25 are referred to herein as the "Director Defendants." The defendants identified in ¶¶18-19, and 25 are referred to herein as the "Audit Committee Defendants." Collectively, the defendants identified in ¶¶14-25 are referred to herein as the "Individual Defendants."

DUTIES OF THE INDIVIDUAL DEFENDANTS

FIDUCIARY DUTIES

27. By reason of their positions as officers and directors of the Company, each of the Individual Defendants owed and owe Trevena and its stockholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage Trevena in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Trevena and not in furtherance of their personal interest or benefit.

28. To discharge their duties, the officers and directors of Trevena were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the financial affairs of the Company. By virtue of such duties, the officers and directors of Trevena were required to, among other things:

(a) ensure the Company complied with its legal and regulatory obligations and requirements, including SEC and FDA obligations and requirements;

(b) ensure honest and good faith interactions with its regulators, including the FDA;

(c) properly and accurately guide investors and analysts as to the true condition of the Company's business, and ensure the Company disseminates truthful and accurate statements to the investing public;

(d) conduct the affairs of the Company in an efficient, business-like manner in compliance with all applicable laws, rules, and regulations so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock; and

(e) remain informed as to how Trevena conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith, and take steps to correct such conditions or practices and make such disclosures as necessary to comply with applicable laws.

BREACHES OF DUTIES

29. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as officers and directors of Trevena, the absence of good faith on their part, and a reckless disregard for their duties to the Company that the Individual Defendants were aware or reckless in not being aware posed a risk of serious injury to the Company.

30. The Individual Defendants breached their duty of loyalty and good faith by allowing defendants to cause, or by themselves causing: (i) the Company to engage in a Phase III study that they knew was inadequately designed; and (ii) to issue improper and misleading public statements and omissions with respect to the Company's business prospects, improper practices causing Trevena to incur substantial damage.

31. The Individual Defendants, because of their positions of control and authority as officers and/or directors of Trevena, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein. The Individual Defendants also failed to prevent the other Individual Defendants from taking such illegal actions. As a result, and in addition to the damage the Company has already incurred, Trevena has expended, and will continue to expend, significant sums of money.

ADDITIONAL DUTIES OF THE AUDIT COMMITTEE DEFENDANTS

32. In addition to these duties, pursuant to its Charter, the Audit Committee

Defendants, defendants Dougherty, Koppel, and Yanni owed specific duties to Trevena to "act on behalf of" the Board in fulfilling the Board's oversight of: (i) the Company's corporate accounting and financial reporting processes, (ii) the Company's systems of internal control over financial reporting and audits of its financial statements, (iii) the quality and integrity of the Company's financial statements and reports, (iv) the qualifications, independence and performance of the registered public accounting firm or firms of certified public accountants engaged as the Company's independent outside auditors for the purpose of preparing or issuing an audit report or performing audit services (the "Auditors") and (v) the performance of the Company's internal audit function. The Committee shall also provide oversight assistance in connection with the Company's legal, regulatory and ethical compliance programs as established by management and the Board.

33. Moreover the Audit Committee's Charter provides that each Audit Committee Defendant has "full access to all books, records, facilities and personnel of the Company as deemed necessary or appropriate by any member of the Committee to discharge his or her responsibilities."

34. The Audit Committee Charter also states that:

> The Committee shall oversee the Company's financial reporting process on behalf of the Board, shall have direct responsibility for the appointment, compensation, retention and oversight of the work of the Auditors and any other registered public accounting firm engaged for the purpose of performing other review or attest services for the Company. The Auditors and each such other registered public accounting firm shall report directly and be accountable to the Committee.... To implement the Committee's purpose and policy, the Committee shall be charged with the following functions and processes with the understanding, however, that the Committee may supplement or (except as otherwise required by applicable laws or rules) deviate from these activities as deemed appropriate under the circumstances:

* * *

Audited Financial Statement Review. To review, upon completion of the audit, the financial statements proposed to be included in the Company's Annual Report on Form 10- K to be filed with the SEC and to recommend to the Board whether or not such financial statements should be so included.

* * *

Quarterly Results. To review and discuss with management and the Auditors, as deemed appropriate, the results of the Auditors' review of the Company's quarterly financial statements, prior to public disclosure of quarterly financial information, if practicable, or filing with the SEC of the Company's Quarterly Report on Form 10-Q, and any other matters required to be communicated to the Committee by the Auditors under standards of the PCAOB.

* * *

Management's Discussion and Analysis. To review and discuss with management and the Auditors, as deemed appropriate, the Company's disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations" in its periodic reports to be filed with the SEC.

Disclosure Committee. To meet with the Disclosure Committee[1] (or a representative thereof), as part of the Committee's regular review of the Company's Form 10-K and Form 10-Q reports (and other filings by the Company with the SEC, when applicable and as deemed necessary, appropriate or desirable by management).

Press Releases. To review and discuss with management and the Auditors, as deemed appropriate, earnings press releases, and press releases containing information relating to material developments as well as the substance of financial information, information relating to material developments and earnings guidance provided to analysts and rating agencies, which discussions may be general discussions of the type of information to be disclosed or the type of presentation to be made.

* * *

Internal Control Over Financial Reporting. To confer with management and the Auditors, as deemed appropriate, regarding the scope, adequacy and effectiveness of the Company's internal control over financial reporting including (a) significant deficiencies or material weaknesses identified by the Company's Auditors, as well as any special steps adopted in light of significant deficiencies or material weaknesses, if any, and the

[1] The Disclosure Committee is a committee consisting of executives at the Company that is supposed to oversee the production of information that is required to be disclosed on a timely basis by Trevena.

adequacy of disclosures about changes in internal control over financial reporting, and (b) any fraud, whether or not material, that involves management or other employees who have any significant role in the Company's internal control over financial reporting.

* * *

Report to Board. To report to the Board of Directors with respect to material issues that arise regarding the quality or integrity of the Company's financial statements, the Company's compliance with legal or regulatory requirements, the performance or independence of the Auditors, the performance of the Company's internal audit function, if applicable, or such other matters as the Committee deems appropriate from time to time or whenever it shall be called upon to do so.

35. The Charter also states that "[t]he approval of this Charter by the Board shall be construed as a delegation of authority to the Committee with respect to the responsibilities set forth herein."

36. In the Company's most recent Proxy, the Board explained:

"Our Audit Committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors compliance with legal and regulatory requirements, in addition to oversight of the performance of our internal audit function."

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

37. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their common plan or design. In addition to the wrongful conduct herein alleged as giving rise to primary liability, the Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

38. The Individual Defendants engaged in a conspiracy, common enterprise, and/or common course of conduct. During this time, the Individual Defendants caused the Company to issue improper financial statements.

39. The purpose and effect of the Individual Defendants' conspiracy, common enterprise, and/or common course of conduct was, among other things, to disguise the Individual Defendants' violations of law, breaches of fiduciary duty, waste of corporate assets, and unjust enrichment; and to conceal adverse information concerning the Company's operations, financial condition, and future business prospects.

40. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company to purposefully or recklessly release improper statements. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

41. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commission of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted in the accomplishment of that wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing.

BACKGROUND ON TREVENA'S DEVELOPMENT OF OLVINO

42. Trevena is a biopharmaceutical company that plans on developing new drugs for the treatment of patients in pain. The Company has never actually completed development of any of its product candidates, and, accordingly, has never achieved profitability. As of September 30, 2018, Trevena had an accumulated deficit of $380.3 million. Throughout the period relevant to this litigation, the Company's main focus was developing the Olinvo Injection. Olinvo was supposed to a treatment for moderate to severe acute pain.

43. Before Trevena could sell Olinvo in the United States, it first had to receive approval of the FDA. The FDA approval process is long, arduous, and expensive. It requires lengthy, expensive, and time-consuming tests and trials. The further a company proceeds through the testing process, the larger, longer, and more expensive the trials become.

44. The first stage in the process is a Phase I trial in which a company tests a medication's safety, appropriate dosage, and side effects on a small group of patients. This is followed by a Phase II trial which uses a larger group of patients to test a drug's effectiveness and side effects. Phase III, normally the final phase in the approval process, uses the largest group of patients. Phase III clinical trials compare the medication to other commonly used treatments and provide further information on the medication's safety and efficacy. According to FDA guidelines and pharmaceutical standards, these trials usually take several years to complete to determine the long-term effects of a medication on patients. If a company has evidence from its early tests, preclinical, and clinical research that a drug is safe and effective for its intended use, the company can apply to receive FDA approval for the drug by filing an NDA with the FDA.

45. The Company initiated its Phase III clinical program for Olinvo in January 2016 and started its pivotal Phase III trial in the second half of 2016 after meeting the FDA for its End of Phase II meeting.[2] At this time, Olinvo was the Company's only drug candidate that had progressed past a Phase I study.

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[2] A "pivotal" trial or study is one that is intended to provide evidence for FDA approval.

THE INDIVIDUAL DEFENDANTS PUSH FORWARD WITH THE PHASE III TRIAL DESPITE OBJECTIONS FROM THE FDA ABOUT THE TRIAL

46. The FDA met with the Company repeatedly throughout 2016 to discuss the Company's clinical development plan, including the design of its Phase III trial for Olinvo. The contents of these meetings was not revealed to investors. During these nonpublic meetings, the FDA repeatedly criticized the Company's clinical development plans. These criticisms covered such basic issues as the Company's phase III study's "endpoints." Endpoints are the measurement by which to assess whether a therapy is effective compared with its control. Without a satisfactory and agreed upon endpoint, the Company could not show that Olinvo actually worked as intended.

47. In particular, the FDA and the Company met on or about February 21, 2016 to discuss Trevena's initial Pediatric Study Plan (IPSP).[3] The FDA told Trevena that it did not agree with the iPSP "due to multiple issues, including the study design (which needed to be changed to an add-on design) and dose selection."

48. On March 3, 2016, the FDA provided instructions regarding the Company's trials after reviewing concerning data from electrocardiographs ("ECG"). The ECGs showed an elongated QT internal, which is associated with abnormal heart rhythms. In particular, the FDA stated:

March 3, 2016 – Advice regarding ECGs – Written Advice

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[3] Due to the lack of studies conducted on the pediatric population, the FDA instituted the pediatric rule in 1998. This rule requires manufactures of certain new and marketed drugs and biologics to conduct studies to support directions for pediatric use for the drug's claimed indications. This rule was subsequently written into law by Congress as the Pediatric Research Equity Act.

> FDA issued written advice to the Applicant because QTcF prolongation exceeded the 10-ms regulatory threshold at clinically relevant exposures. The Applicant was instructed to submit amendments to modify all protocols for ongoing clinical trials to include the following safety assessments, and incorporate them into any future clinical trials:
> 1. Conduct safety ECG monitoring at baseline, following the first dose, and periodically thereafter. The timing of ECGs will need to reflect the delayed response relative to time of peak concentrations that was observed in the thorough QT study. Include additional ECG monitoring until ECGs return to baseline in patients discontinued from the trial or requiring dose reduction due to QTc interval prolongation.
> 2. Periodic monitoring of electrolytes (subjects already participating in the study with serum potassium, magnesium, or calcium levels outside of the central laboratory's reference range should be carefully monitored and brought to normal values).
> 3. Propose dose-modification and discontinuation criteria in subjects with posttreatment QTc > 500 ms or post-baseline increases > 60 ms.

49. On March 29, 2016, the FDA held its End-of-Phase II Meeting with Trevena, during which they discussed Company's proposed Phase III studies. The FDA provided its sharpest criticism of Trevena's plans yet. Among other issues, the FDA did not agree with the Company's proposed endpoint "as it was unclear how [the proposed endpoint] correlates to an improvement in pain intensity scores…and if that change is clinically relevant." The FDA also did not agree with the proposed dosing in the Phase III studies. In particular, the minutes from that meeting stated:

> **March 29, 2016 (meeting minutes April 28, 2016) –End-of-Phase 2 Meeting**
>
> • FDA did not agree with the proposed dosing in the Phase 3 studies. The Sponsor proposed dosing up to 100 mg daily (including a 0.75 mg every 1 hour as needed clinician administered dose), but had only studied maximum daily doses of 36.8 mg. Further, the Sponsor did not have adequate non-clinical support for the proposed doses.
> • FDA did not agree with the proposed primary endpoint, as it was unclear how a 30% improvement from baseline based on SPID correlates to an improvement in pain intensity scores on the NRS in the proposed setting of acute postoperative pain and if that change is clinically relevant.
> • FDA did not agree with the proposed non-inferiority (NI) margin for comparing morphine to olicerıdine.

> • FDA noted that the safety database must include at least 350 patients exposed to the highest intended dose for the longest expected duration of use. It was noted that the safety database requirements might change if safety signals arise during development that require further evaluation.
> • Any comparative safety claims must be replicated, adequately justified for clinical relevance, and established in the setting of comparable efficacy between comparators to be considered for inclusion in labeling
> • The Applicant provided details of a proposed approach to missing data. This approach included replacing pain scores in the window determined dosing interval described in the label of the rescue medication following rescue with the pain score recorded immediately prior to rescue.

50. On May 6, 2016, the Company provided its justification for its primary endpoint, explaining that the 30% improvement for base was the midpoint between the placebo effect and the results for morphine. The FDA did not express agreement with this endpoint. Further, as the FDA later explained, "[t]his endpoint is novel and has never been the basis for approval for any drugs in this class." Nevertheless, Trevena pushed forward with the Phase III study using its chosen endpoint.

51. On November 8, 2016, Trevena and the FDA met again to discuss the Company's trials of Olinvo. Again, the FDA explained to Trevena's that its proposed trials were flawed and would not provide the clinical data to test whether Olinvo was safe. Among other things, the FDA explained that the results would not show clinical significance. In particular, the FDA's meeting minutes explained:

> **November 8, 2016 (meeting minutes December 19, 2016) – Type C teleconference**
>
> • FDA did not agree with Trevena's proposal to evaluate the respiratory safety of oliceridine as compared to morphine because the definition of Respiratory Safety Events (RSEs) was not clearly defined and the determination of the presence of an RSE relied largely on clinical acumen. Even though the parameters proposed in the evaluation of an RSE (respiratory rate, oxygen saturation, and MRPSS somnolence/sedation scores) are well accepted criteria used for the assessment of patients at risk for experiencing an RSE, it is unclear that a small change in these parameters is of clinical significance. Trevena was told to specify a clinically meaningful definition of an RSE, such as patients who require a clinical intervention after meeting a specific criterion (e.g., naloxone administration

> and/or oxygen administration with a reduction in oxygen saturation). Further, FDA did not agree with inclusion of sedation and somnolence in the RSE definition.
> • FDA stated that the statistical model proposed to evaluate the respiratory safety of oliceridine incorporates both the population prevalence of RSEs and the population conditional mean cumulative duration of RSEs to describe respiratory safety burden (RSB). Based on this model, a small change in event duration could result in a statistically significant result without clinical significance. In addition, the RSB endpoint is difficult to interpret and apply directly to clinical practice. Trevena was asked to analyze and report event duration separately from the event prevalence.

52. On May 5, 2017, the FDA again raised concerns about the Company's plan to show Olinvo's respiratory safety. The meeting minutes noted that the "FDA reiterated the concerns noted at the November 8, 2016, teleconference regarding the assessment of respiratory safety" and that the "statistical plan would be considered exploratory ***and would not be acceptable*** for a proposed labeling claim."

53. The FDA continued to meet with Trevena throughout 2017, as the Company prepared its NDA. On November 7, 2017, Trevena announced that it had recently submitted the NDA.

54. On October 9, 2018, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee issued a Briefing Document in advance of its previously scheduled October 11, 2018, meeting to vote on its recommendation to the FDA concerning its approval of Olinvo (the "Briefing Document"). The Briefing Document discussed the various flaws in the methodology behind the Phase III study and the FDA's constant complaints to Trevena about the study. It also showed that the control drug (morphine) worked just as well or better than Olinvo. Addressing the primary endpoint of the Company's phase III studies, the Briefing Document explained, "This endpoint is novel and has never been the basis for approval for any drugs in this

class. Consequently, sensitivity analyses were also performed directly on the SPID scores which are typically used as the primary efficacy endpoint in this setting."

55. Regarding the key secondary safety endpoint, the occurrence and duration of respiratory safety events, the Briefing Document explained, "there is no precedent for use of this endpoint in a clinical study and the FDA did not agree that this was a clinically interpretable endpoint for the evaluation of a potential respiratory claim. During development, FDA informed the Applicant that their definition of RSE was not clearly defined and relied largely on clinical acumen."

56. As a result of the Company using a novel primary efficacy that it disagreed with, the FDA disregarded it and used its own analysis. The FDA also disagreed with how Trevena dealt with patients that needed to use rescue mediation in its analysis and therefore the FDA conducted its own alternative analysis there as well. As the Briefing Document explained:

> Since the Applicant's primary efficacy analyses was based on a novel responder definition, i.e. 30% improvement in SPIDs, FDA conducted an analysis using SPIDs rather than the proposed responder definition. FDA disagreed with how information regarding use of rescue medication was used in the Applicant's derivation of SPIDs. Carrying forward the final prerescue score from the first use of rescue until the end of the observation period ignores the fact that the effect of the rescue medication will expire, and the fact that patient's pain scores would continue to improve throughout the study even in the placebo arm. The consequence is that it harshly penalizes patients who used rescue medication. FDA used an alternative analysis which carries forward the pre-rescue scores for the dosing interval of the rescue medication, which is commonly used in studies of analgesics in the post-surgical setting, and considered the most clinically relevant.

57. With regards to the secondary efficacy analysis, which was that Olinvo was not inferior to morphine, the Briefing Document noted that the FDA and the Company never reached an agreement on what "non-inferiority" meant a critical component of the NDA. In particular, the Briefing Document explained:

Secondary Efficacy Analysis:
• Non-inferiority assessment of oliceridine to morphine: While this is critical in light of the application's objective of demonstrating a reduction in the respiratory safety burden for oliceridine compared to morphine, there was no agreement on the Applicant's definition of the non-inferiority criteria.

58. As could be expected from the Briefing Document, the Advisory Committee voted against recommending the approval of Olinvo. Then, on November 2, 2018, Trevena announced that it received a Complete Response Letter ("CRL") from the FDA. The FDA's CRL refused to approve Olinvo and requested "additional clinical data on QT prolongation and indicated that the submitted safety database is not of adequate size for the proposed dosing. The FDA also requested certain additional nonclinical data and validation reports." Each of the issues raised in the CRL was also raised with the Company during meetings with the FDA, as shown by the Briefing Document.

59. On November 8, 2018, the Company announced it would reduce its workforce by approximately one-third and undergo a reorganization.

IMPROPER STATEMENTS

60. Despite the guidance from the FDA, Trevena continuously made improper statements about the status of its Phase III trials, its discussions with the FDA, and the impending success of Olinvo. In particular, on May 2, 2016, Trevena issued a press release entitled "Trevena Announces ***Successful End-of-Phase 2 Meeting with FDA1*** and Outlines Phase 3 Program for Oliceridine." Among other things, the press release claimed that the Company reached a "general agreement on key elements of the Phase 3 program," despite the FDA questioning fundamental aspects of the phase III trial's design. In particular, the press release stated:

> *– Pivotal efficacy studies to start in 2Q 2016, with topline data expected in 1Q 2017, and NDA filing expected in 2H 2017 –*

– Phase 3 program includes comparisons to both placebo and morphine

· Webcast and call scheduled for today at 5:30 pm EDT

. . . Trevena . . . today announced the successful completion of the End-of-Phase 2 Meeting process with the United States Food and Drug Administration (FDA). ***The company has reached general agreement with the FDA on key elements of the Phase 3 program to support a New Drug Application (NDA) for oliceridine (TRV130), to which the FDA has granted Breakthrough Therapy designation.***

"We are very pleased with the outcome of our End-of-Phase 2 discussion with the FDA," said Maxine Gowen, Ph.D., chief executive officer. ***"We appreciate the valuable guidance the FDA has provided, and look forward to continuing a constructive relationship*** as we advance our Phase 3 registration program. We remain focused on bringing oliceridine to market as a new and potentially differentiated analgesic for patients and caregivers seeking alternatives to conventional opioids."

End-of-Phase 2 meeting

The FDA agreed that pivotal efficacy trials in bunionectomy and abdominoplasty patients include appropriate patient populations to support an indication for moderate to severe acute pain. The agency also confirmed the need for at least 1,100 patients exposed to oliceridine across the development program for the purposes of evaluating safety and tolerability. This database should include a sufficient number of patients with higher exposures and longer durations of oliceridine therapy. In addition, general agreement was reached on the company's planned clinical, nonclinical, clinical pharmacology, and chemistry, manufacturing and control (CMC) activities to support the planned NDA.

Overview of the Oliceridine Phase 3 program

- The oliceridine Phase 3 program includes two pivotal efficacy trials evaluating moderate-to-severe acute pain: the APOLLO-1 study will evaluate pain for 48 hours following bunionectomy, and the APOLLO-2 study will evaluate pain for 24 hours following abdominoplasty. In each trial, patients will be randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) for the management of their post-operative pain. Each study will enroll approximately 375 patients, allocated equally across study arms.

- *The primary endpoint for both APOLLO studies will be a responder analysis proposed by the company comparing active treatment arms to placebo A responder is defined as a patient experiencing a sum of pain intensity difference (SPID) at the end of the treatment period that*

corresponds to at least a 30% improvement from baseline without early discontinuation and without rescue pain medication.

- ***Secondary endpoints in both APOLLO studies will include comparisons of oliceridine efficacy, safety, and tolerability to morphine.*** A respiratory safety endpoint will measure prevalence and duration of hypoventilation, which will be a clinical assessment as in the company's Phase 2b abdominoplasty study.

- The APOLLO study designs were informed in part by the company's Phase 2b abdominoplasty study, which also used PCA dosing. Powering assumptions included similar performance of PCA-administered oliceridine in both APOLLO studies as was observed in the Phase 2b study. In a post- hoc evaluation using the Phase 3 responder analysis, both doses in the company's Phase 2b study in abdominoplasty yielded analgesic efficacy similar to morphine, and significantly higher than placebo ($p \leq 0.0005$ for both oliceridine treatment arms). In addition, using the Phase 3 respiratory safety endpoint, both doses in the company's Phase 2b study showed significantly less respiratory safety burden for oliceridine than morphine ($p \leq 0.0003$ for both oliceridine treatment arms).

- The development program will include at least 1,100 patients exposed to oliceridine. The on-going open-label ATHENA-1 safety study is enrolling patients experiencing pain as a result of either a medical diagnosis or surgery. In this study, patients may receive oliceridine as-needed either as an intermittent bolus or via PCA device, with doses and durations appropriate to manage their pain.

Both APOLLO-1 and APOLLO-2 are expected to start in the second quarter of this year, and the company expects to report top-line data in the first quarter of 2017. The company continues to expect to file an NDA for oliceridine in the second half of 2017. The company also continues to expect that its available cash and investments will be sufficient to fund operations into 2018.

61. Defendants Violin, Gowen and Soergel conducted a conference with investors and stock analysts that same day. During her remarks, defendant Gowen claimed to have had a "successful discussion" with the FDA concerning the design of the Phase III clinical trial of Olinvo. In particular, she stated:

> As many of you know, oliceridine is the first pain program awarded breakthrough therapy designation by the FDA. We were granted this important distinction on the basis of our Phase 2 data in which oliceridine matched the pain relieving power of morphine ***but with faster onset, less nausea and vomiting, and fewer respiratory safety events.***

> This has supported what we've long believed about oliceridine. It is a new class of analgesic molecule, muGPS, that harnesses innovative science to offer the potential for powerful pain relief with better safety and tolerability than conventional opioid analgesics like morphine. ***We welcome the opportunity to work with the FDA to finalize our Phase III plans. I am pleased to report that we had a very productive and collaborative and successful discussion of our oliceridine program with the FDA. This was the only helpful as we transition the program into Phase III, but I'm sure will be invaluable as we continue our conversation through the NDA.***

62. On May 5, 2016, Trevena issued a press release announcing its first quarter 2016 financial results for the interim period ended March 31, 2016. Concerning the status of the Company's Phase III clinical trial of Olinvo, the press release stated:

> "The first quarter set the stage for a critical year in Trevena's evolution," said Maxine Gowen, Ph.D., chief executive officer. "***We had a successful End-of-Phase 2 discussion of oliceridine with the FDA, and look forward to completing our ongoing Phase 3 program aimed at both approval and differentiation of oliceridine for moderate to severe acute pain.*** . . .
>
> **First Quarter and Recent Highlights**
>
> - **Received Breakthrough Therapy Designation for oliceridine.** In February, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to the company's lead product candidate, intravenous oliceridine (TRV130), for the management of moderate-to-severe acute pain. Breakthrough Therapy designation is granted by the FDA to new therapies intended to treat serious conditions, and for which preliminary clinical evidence indicates that the drug may demonstrate substantial clinical improvement over available therapies. The company believes this is the first Breakthrough Therapy designation for a pain therapy.
>
> - ***Conducted a successful End-of-Phase 2 meeting for oliceridine with the FDA and announced details of the Phase 3 clinical program.*** Earlier this week, the company announced that it had ***reached agreement with the FDA on key elements of the Phase 3 program*** to support a New Drug Application (NDA) for oliceridine. The company also provided additional details of the Phase 3 clinical program, which will include two 375-patient, randomized, double-blind, placebo- and active-controlled, pivotal efficacy trials: the APOLLO-1 study, which will evaluate pain for 48 hours following bunionectomy; and the

> APOLLO-2 study, which will evaluate pain for 24 hours following abdominoplasty. In each trial, patients will be randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) for the management of their post-operative pain, with approximately 75 patients enrolled per study arm. ***The primary endpoint for both APOLLO studies will be a responder analysis comparing active treatment arms to placebo. Secondary endpoints in both APOLLO studies will include comparisons of oliceridine efficacy, safety, and tolerability to morphine.***

> In January, the company initiated the Phase 3 clinical program with the enrollment of patients in the open label ATHENA study, which is evaluating the safety and tolerability of oliceridine in patients with moderate-to-severe acute pain caused by medical conditions or surgery. Patients will be treated with oliceridine on an as- needed basis via IV bolus, PCA administration, or both, as determined by the investigator.

> The company expects to start the APOLLO studies in the second quarter of this year, and to report top-line data from these studies in the first quarter of 2017. The company continues to expect to file an NDA in the second half of 2017.

63. On June 8, 2016, Trevena issued a press release entitled "Trevena, Inc. Announces First Patients Enrolled in the APOLLO-1 and APOLLO-2 Phase 3 Pivotal Efficacy Studies of Oliceridine in Acute Pain." The press release stated:

> · *Trials include comparisons of efficacy, safety and tolerability of oliceridine to both placebo and morphine*
>
> - *Top-line data for both studies expected in 1Q 2017*
>
> Trevena . . . today announced the enrollment of the first patients in the Phase 3 APOLLO-1 and APOLLO-2 studies of oliceridine in patients suffering moderate to severe acute pain following bunionectomy and abdominoplasty, respectively.
>
> "We are pleased to announce the start of the APOLLO studies, ***which we designed both to support approval of oliceridine and to confirm the potential differentiation of oliceridine from conventional opioids***," commented Maxine Gowen, Ph.D., chief executive officer. ***"The trials recapitulate many features of our successful Phase 2 studies, with refinements based on the full Phase 2 data set that we believe strengthen the study designs and improve our probability of success.*** Together with the ongoing ATHENA Phase 3 safety study, ***we believe the APOLLO studies position us to deliver a robust data package to support regulatory approval and commercial success***."

> The company continues to expect to report top-line data from both APOLLO studies in the first quarter of 2017, and to file an NDA for oliceridine in the second half of 2017. The company also continues to expect that its available cash and investments will be sufficient to fund operations into 2018.
>
> **About the Apollo-1 and Apollo-2 Studies**
>
> Both APOLLO trials are phase 3, multicenter, randomized, double-blind, placebo- and active-controlled studies of oliceridine for the treatment of moderate to severe acute pain. The APOLLO-1 study will evaluate pain for 48 hours following bunionectomy, and the APOLLO-2 study will evaluate pain for 24 hours following abdominoplasty. In each trial, patients will be randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia
>
> (PCA) device for the management of their post-operative pain. Each study will enroll approximately 375 patients, allocated equally across study arms. ***The primary objective in each study is to evaluate the analgesic efficacy of oliceridine compared to placebo. Secondary endpoints will include comparisons of oliceridine efficacy, safety, and tolerability to morphine.***

64. That same day, Defendant Gowen made a presentation at the Jefferies Healthcare Conference. During the presentation, defendant Gowen discussed the "clinically significant endpoints" that showed the "substantial improvement" of Olinvo over other available therapies. Defendant Gowen also claimed that the FDA agreed with the Company that the Phase III trials could provide sufficient data to support the approval of Olinvo. In particular, she stated:

> So this breakthrough therapy designation was the first that had ever been given to a pain drug . . . .
>
> Just to remind you of the qualifying criteria, that the drug is intended to treat a serious condition, clearly pain falls into that category. ***And there is preliminary clinical evidence indicating the drug may demonstrate substantial improvement on a clinically significant endpoint or endpoints over available therapies. And here the FDA was considering its differentiation to conventional opioid drugs.***
>
> So there is still a strong need that physicians express for better and safer options to treat acute pain. It still remains undertreated despite the introduction of so-called multimodal therapy, which is the addition of other therapies onto opioid therapies.

* * *

One of the reasons for this under treatment of pain is because conventional opioids, which are the foundation of pain therapy, are used sparingly because of their side effects. Post-operatively we see nausea and vomiting in a high percentage of patients. This is very distressing and uncomfortable for the patients.

But we also see a safety issue with respect to respiratory depression. And there is a high incidence of respiratory depression or rather a high number even though the incidence is relatively low. And this can certainly be fatal and it is fatal in tens of thousands of patients every year in the United States.

So, oliceridine, acting through this biased ligand approach, activates the G protein pathway in this case, which is the pathway leading to analgesic efficacy, very low levels of activation of the beta-arrestin pathway. And this leads to an enhancement of analgesia, a decrease in the opioid-related adverse events, significantly increasing the therapeutic window of the drug.

So the goal is to find doses of the drug that are highly efficacious but have significantly reduced side effects. And that is indeed what we showed recently in a Phase 2b clinical trial.

* * *

So we are looking at three effects: nausea, vomiting and hypoventilation. And hypoventilation is a measure of respiratory suppression. So these were a lot less prevalent in the oliceridine treated patients than with morphine for all three of these. And they were indeed statistically significantly less than the incidence with morphine.

And these are both statistically meaningful and clinically very meaningful reductions inside -- in these key side effects. ***So, we really believe that we have breakthrough potential of oliceridine versus the conventional IV opioids. We have great efficacy. We have excellent precision.***

…. And in terms of safety we are seeing less hypoventilation, less nausea and less vomiting with oliceridine.

So, we had an end of Phase 2 meeting with the FDA at the very end of March. ***And we reached agreement with them that we have shown sufficient data to move into Phase 3. The program that we proposed to them they agreed would support an approval -- could support, I should say given that the data are correct, could support an approval for the target indication.***

* * *

The key elements of the Phase 3 program are two pivotal efficacy studies with PCA dosing as I -- in the study that I just showed you in Phase 2, to support

efficacy. And these two studies will be performed in the two surgical types that we already studied in Phase 2 with successful outcomes. So, bunionectomy is a hard tissue, abdominoplasty a soft tissue. And this is what allows us to get this broad label.

65. On August 4, 2016, Trevena issued a press release announcing its second quarter 2016 financial results for the interim period ended June 30, 2016. Concerning the status of the Company's Phase III clinical trial of Olinvo, the press release stated:

"This quarter marked an important milestone for the company's oliceridine program with the initiation of our two Phase 3 pivotal efficacy trials," said Maxine Gowen, Ph.D., chief executive officer. "***Following our successful End-of-Phase-2 and Breakthrough Therapy designation meeting with the FDA in the first quarter***, we were able to rapidly initiate the pivotal efficacy trials, which are enrolling well."

Second Quarter and Recent Highlights

- **Enrolled first patients in APOLLO-1 and APOLLO-2 Phase 3 trials of oliceridine.** In June, the company announced the enrollment of the first patients in the APOLLO-1 and APOLLO-2 pivotal Phase 3 efficacy studies. APOLLO-1 is studying patients suffering moderate to severe pain for 48 hours after undergoing bunionectomy, while APOLLO-2 is studying patients suffering moderate to severe pain for 24 hours after undergoing abdominoplasty; both are 375-patient, multicenter, randomized, double-blind, placebo- and active-controlled studies. Patients are randomized to receive placebo, morphine, or one of three oliceridine regimens, all dosed as needed via patient-controlled analgesia (PCA) device for the management of their post-operative pain, with approximately 75 patients per study arm. ***The primary objective of both trials is to evaluate the analgesic efficacy of oliceridine versus placebo. Secondary endpoints compare the efficacy, safety, and tolerability of oliceridine to morphine.*** The company continues to expect to release top-line data in the first quarter of 2017 and to file an NDA in the second half of 2017.

66. On November 3, 2016, Trevena issued a press release announcing its third quarter 2016 financial results for the interim period ended October 31, 2016. The release stated:

"This quarter saw important progress for our company, ***with continued execution of our Phase 3 program for oliceridine***. We had extensive engagement with the medical community to discuss the challenges of acute pain management in the hospital and how oliceridine may provide an important treatment option to patients and physicians," said Maxine Gowen, Ph.D., chief executive officer. "We

look forward to sharing top-line data from both Phase 3 APOLLO pivotal efficacy studies in the first quarter of 2017, and filing an NDA in the second half of next year."

Third Quarter and Recent Highlights

- **APOLLO-1 and APOLLO-2 Phase 3 efficacy trials of oliceridine remain on track for first quarter 2017 topline data release.** The APOLLO-1 trial includes patients suffering moderate to severe pain after undergoing bunionectomy, while the APOLLO-2 trial includes patients suffering moderate to severe pain after undergoing abdominoplasty; both are 375-patient, multicenter, randomized, double-blind, placebo- and active-controlled studies. Patients are randomized to receive placebo, morphine, or one of three oliceridine regimens, all dosed as needed via patient- controlled analgesia (PCA) device for the management of their post-operative pain, with approximately 75 patients per study arm. ***The primary objective of both trials is to evaluate the analgesic efficacy of oliceridine versus placebo. Secondary endpoints compare the efficacy, safety, and tolerability of oliceridine to morphine.***

67. On January 4, 2017, Trevena issued a press release entitled "Trevena Completes Enrollment of Phase 3 APOLLO Pivotal Efficacy Trials of Oliceridine for Moderate-to-Severe Acute Pain." The press release stated:

- Top-line results expected later this quarter –

Trevena . . . today announced that it has completed enrollment of its Phase 3 APOLLO-1 and APOLLO-2 pivotal efficacy studies of oliceridine (TRV130) in moderate-to-severe acute pain following bunionectomy and abdominoplasty, respectively.

"***We are pleased to have completed enrollment in these important studies*** and to confirm that the APOLLO trials remain on schedule to report top-line results in the first quarter of 2017," said Maxine Gowen, Ph.D., chief executive officer. "***We look forward to sharing these data when they become available.***"

The APOLLO studies were designed based on the Phase 2 clinical trials of oliceridine that were successful in showing potential differentiation of oliceridine from morphine. The Company expects top-line results to include measures of efficacy, safety, and tolerability of oliceridine compared to both placebo and morphine.

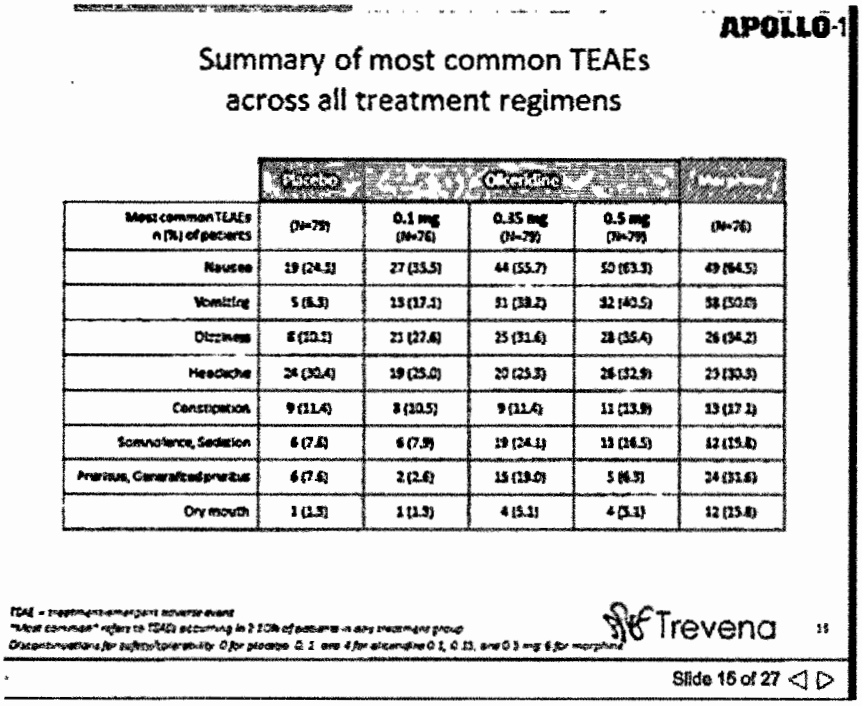
In addition, the Company announced that patient enrollment for the Phase 3 ATHENA multi-procedure safety study remains on track. The Company

continues to anticipate filing a New Drug Application (NDA) for oliceridine with the U.S. Food & Drug Administration (FDA) in the second half of 2017.

About The Apollo-1 And Apollo-2 Studies

Both APOLLO trials are Phase 3, multicenter, randomized, double-blind, placebo- and active-controlled studies of oliceridine for the treatment of moderate to severe acute pain. The APOLLO-1 study is evaluating pain for 48 hours following bunionectomy, and the APOLLO-2 study is evaluating pain for 24 hours following abdominoplasty. In each trial, patients were randomized to receive placebo, morphine, or one of three regimens of oliceridine by patient-controlled analgesia (PCA) device for the management of their post-operative pain. Each study enrolled approximately 375 patients, allocated equally across study arms. ***The primary objective in each study is to evaluate the analgesic efficacy of oliceridine compared to placebo. Secondary endpoints include comparisons of efficacy, safety, and tolerability of oliceridine to morphine.***

68. Before the opening of trading on February 21, 2017, Trevena issued a press release announcing the clinical results of the APOLLO-1 and APOLLO-2 Phase 3 clinical trials of Olinvo. The results were not positive for the Company. While the highest of the three doses of Olinvo demonstrated a statistically superior rate of pain relief compared to morphine, it conceded that the lowest dose had not. It was only this lowest dose, however, that demonstrated a statistically meaningful lower rate of depressed breathing compared to morphine. In addition, Olinvo did not cause a significantly significant decrease in vomiting and nausea compared to morphine. In particular, the press release stated:



APOLLO-1

Summary of most common TEAEs across all treatment regimens

Most common TEAEs n [%] of patients	Placebo (N=79)	Olinvo 0.1 mg (N=76)	Olinvo 0.35 mg (N=79)	Olinvo 0.5 mg (N=79)	Morphine (N=76)
Nausea	19 (24.1)	27 (35.5)	44 (55.7)	50 (63.3)	49 (64.5)
Vomiting	5 (6.3)	13 (17.1)	31 (39.2)	32 (40.5)	38 (50.0)
Dizziness	8 (10.1)	21 (27.6)	25 (31.6)	28 (35.4)	26 (34.2)
Headache	24 (30.4)	19 (25.0)	20 (25.3)	26 (32.9)	23 (30.3)
Constipation	9 (11.4)	8 (10.5)	9 (11.4)	11 (13.9)	13 (17.1)
Somnolence, Sedation	6 (7.6)	6 (7.9)	19 (24.1)	13 (16.5)	12 (15.8)
Pruritus, Generalized pruritus	6 (7.6)	2 (2.6)	15 (19.0)	5 (6.3)	24 (31.6)
Dry mouth	1 (1.3)	1 (1.3)	4 (5.1)	4 (5.1)	12 (15.8)

TEAE = treatment-emergent adverse event
"Most common" refers to TEAEs occurring in ≥ 10% of patients in any treatment group
Discontinuations for safety/tolerability: 0 for placebo; 2, 1, and 4 for alvimopan 0.1, 0.35, and 0.5 mg; 6 for morphine

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69. During a conference call all later that day, defendant Gowen revealed for the first time – that "[a] particular challenge was including morphine as a comparator in the trial, not the norm in our industry . . . ." Defendant Soergel disclosed that the Company was no longer on track to file its NDA between July and September 2017, and would instead not be in a position to file it until October 2017 at the earliest.

70. On March 8, 2017, Trevena issued a press release announcing its fourth quarter and fiscal year 2016 financial results for the period ended December 31, 2016. The release highlighted the purportedly "**Successful End-of-Phase 2 meeting with FDA**," stating that:

> In May 2016, ***the Company announced that it had reached general agreement with the FDA on key elements of the Phase 3 OLINVO program to support a New Drug Application (NDA), including that the APOLLO-1 and APOLLO-2 pivotal efficacy trials in bunionectomy and abdominoplasty included appropriate patient populations to support an indication for moderate-to-severe acute pain.***

71. Defendant Gowen, in the press release, stated that "***[t]he recent successful completion of the pivotal efficacy studies for OLINVO put[] [Trevena] in a strong position to***

bring this innovative analgesic to physicians and patients in need of a new option for managing moderate-to-severe acute pain in the hospital," adding that Trevena then "believe[d] the data from these studies highlight the potential for OLINVO to reduce the burden of opioid-related adverse effects, particularly for those patients who [were] at elevated risk for serious consequences from post-operative nausea and vomiting or opioid-induced respiratory depression."

72. On March 8, 2017, Trevena filed its Annual Report on Form 10-K with the SEC for the fiscal year ended December 31, 2016 (the "2016 Form 10K"). The 2016 Form 10-K was signed by defendants Gowen, Moulder, Dougherty, McHugh, Nunn, Philips, Yanni, Cuca and Koppel. Concerning the Phase III clinical trial, defendants Gowen, Moulder, Dougherty, McHugh, Nunn, Philips, Yanni, Cuca and Koppel stated in the 2016 Form 10-K stated:

> *Phase 3 development program*
>
> In January 2016, we initiated the Phase 3 clinical program for OLINVO with the enrollment of patients in the ATHENA study, a Phase 3, open label, multicenter study evaluating the safety and tolerability of OLINVO in approximately 900 patients. The study is enrolling eligible patients with moderate-to-severe pain caused by medical conditions or surgery. Patients are treated with OLINVO on an as-needed basis via IV bolus, patient-controlled analgesia, or PCA, or both, as determined by the investigator. ***The primary objective is to assess the safety and tolerability of OLINVO. Pain intensity is being measured as a secondary endpoint.*** As of February 15, 2017, over 400 patients have been treated in the ATHENA study, with no apparent off-target or unexpected adverse effects.
>
> In the first quarter of 2016, we discussed our Phase 3 development program with the FDA at an End of Phase 2 meeting. ***At this meeting, the FDA agreed that pivotal efficacy trials in bunionectomy and abdominoplasty patients include appropriate patient populations to support an indication for the management of moderate-to-severe acute pain.***
>
> ***The FDA also confirmed the need for at least 1,100 patients exposed to OLINVO across the development program for the purposes of evaluating safety and tolerability and that the trials should include a sufficient number of patients with higher exposures and longer durations of OLINVO therapy. In addition, general agreement was reached on our planned clinical, nonclinical,***

clinical pharmacology, and chemistry, manufacturing and control activities to support the planned NDA.

* * *

Commercialization

We intend to build hospital commercial capabilities in the United States and retain full U.S. rights to OLINVO. We expect to seek collaborators to commercialize OLINVO outside the United States to offset risk and preserve capital.

To commercialize OLINVO in the United States, we intend to utilize a hospital-focused specialty sales force targeting surgeons, anesthesiologists, hospitalists, and other healthcare providers with acute post-surgical or medical pain management responsibility. Within the inpatient setting, we believe that there will be opportunities for OLINVO in the post-anesthesia care unit, the emergency department, the intensive/critical care unit, and the medical/surgical floor. Based on market research conducted to date with key customers, we currently expect to focus on multiple surgical and medical procedures in which OLINVO may be a good clinical fit due to patient or procedure characteristics. In targeted hospitals, we will work to secure Pharmacy and Therapeutics Committee approval and subsequent pull- through utilization of OLINVO. Given the changing dynamics in the hospital marketplace and the increased emphasis on clinical and economic outcomes, we expect our commercialization plans also will include health economic information designed to demonstrate the value OLINVO could provide to the healthcare system through a potential reduction in adverse events related to the use of conventional IV opioids. ***Because many of our targeted customers also provide care in other hospital settings, we anticipate that we will also target a select number of hospital outpatient departments and ambulatory surgery centers.***

73. On March 27, 2017, defendant Bourdow made a presentation at the Oppenheimer Healthcare Conference. During the conference, defendant Bourdow stated that "all three dosing regimens of Olinvo were statistically significant over placebo and so that gives us great confidence that this drug is approvable and that we can apply for that broad indication statement at the top: for the management of moderate to severe acute pain." Defendant Bourdow also claimed that Olinvo was safer than morphine, stating "Here what you see is that all three dosing regimens of Olinvo had fewer safety events versus morphine."

74. On May 4, 2017, Trevena issued a press release announcing its first quarter 2017 financial results for the interim period ended March 31, 2017. The release stated:

> "***This quarter marked a key milestone for our OLINVO program, with the delivery of robust data that we believe will support our new drug application and demonstrates the potential value of OLINVO for the management of moderate-to- severe acute pain in the hospital,***" said Maxine Gowen, Ph.D., chief executive officer. "There remains a critical unmet need for patients who require IV opioids to manage pain but are at risk for poor outcomes from opioid-related adverse effects. ***Our successful Phase 3 data showed not only significant efficacy of OLINVO versus placebo to support approval, but also showed the potential for fewer gastrointestinal and respiratory adverse effects while providing comparable pain relief to a commonly used morphine regimen.***"
>
> **First Quarter and Recent Corporate Highlights**
>
> - **Announced positive top-line results from two Phase 3 pivotal efficacy studies of OLINVOTM (oliceridine injection) for moderate-to-severe pain.** In February, the Company announced ***positive data*** from the APOLLO- 1 and APOLLO-2 studies of OLINVO in moderate-to severe-acute pain following hard tissue and soft tissue surgeries, respectively. OLINVO demonstrated significant analgesic efficacy compared to placebo in both studies for all three tested dosing regimens. ***Consistent with Phase 2b results, a 0.35 mg dose regimen provided comparable pain relief to a common IV morphine regimen and showed potential to reduce opioid-related adverse effects on multiple measures of respiratory safety and gastrointestinal tolerability.***
>
> - **OLINVO program remains on track for a new drug application (NDA) submission in 4Q 2017.** As of March 31, 2017, approximately 600 patients have been treated with OLINVO in the ongoing open-label, multi-procedure ATHENA safety study. In addition, the Company has successfully completed a chemistry, manufacturing, and controls Type B pre-NDA meeting with the U.S. Food and Drug Administration (FDA), and ***all pre-NDA activities remain on track*** to support an NDA submission to the FDA in the fourth quarter of 2017.

75. On August 3, 2017, Trevena issued a press release announcing its second quarter 2017 financial results for the interim period ended June 30, 2017. The press release stated:

> "The second quarter saw ***continued progress towards our goal of delivering*** an innovative new option for patients who are at risk of adverse events associated with IV opioids like morphine," said Maxine Gowen, Ph.D., chief executive officer. "***We have now completed our Phase 3 clinical development for OLINVO and successfully completed our pre-NDA meetings with the FDA***. In addition,

we have refined our commercial strategy to lay the groundwork for a successful commercial launch. ***With the comparative data from our successful APOLLO pivotal efficacy studies, as well as data and investigator observations from more real-word use in the ATHENA open label study, we believe the value of OLINVO will resonate with potential prescribers who want to improve the care of hospital patients suffering severe pain***."

Second Quarter And Recent Corporate Highlights

- **OLINVO™ (oliceridine injection) program remains on track for a new drug application (NDA) submission in September/October 2017.** In July 2017, the Company announced that enrollment in the ATHENA open-label safety study was complete to support the NDA file, with 772 patients treated with OLINVO across more than 40 sites. ***In addition, the Company successfully completed a chemistry, manufacturing, and controls (CMC) Type B pre-NDA meeting and a preclinical and clinical Type B pre-NDA meeting with the U.S. Food and Drug Administration (FDA). All pre-NDA activities remain on track*** to support an NDA submission to the FDA in September/October of 2017.

76. On November 7, 2017, Trevena issued a press release announcing its third quarter 2017 financial results for the interim period ended September 30, 2017. The press release stated:

"The recent submission of the OLINVO NDA capped a transformative period for our Company," said Maxine Gowen, Ph.D., chief executive officer. "***We are now focused on preparing for the approval and commercialization of OLINVO***, while continuing to advance our development pipeline following our recent strategic decision to halt our discovery research efforts. ***To this end, new results continue to highlight the potential value of OLINVO for patients in a real world setting who require IV opioids but are at risk of opioid-related adverse events.*** Positive interim Phase 1 data for TRV250 bode well for future clinical development of this exciting potential migraine therapy."

Third Quarter and Recent Corporate Highlights

- **OLINVO New Drug Application submitted. The Company recently submitted its New Drug Application (NDA) for OLINVO to the U.S. Food and Drug Administration (FDA).** OLINVO is the first G protein biased ligand of the mu opioid receptor, a new class of opioid receptor modulator, and the first pain program to receive Breakthrough Therapy designation from the FDA. ***The submission includes data showing that intravenous OLINVO demonstrated analgesic efficacy in all three dosing regimens tested in the two Phase 3 APOLLO pivotal efficacy studies. These trials were designed to support an indication for the management of moderate-to-severe acute pain in adult patients for whom an intravenous opioid is warranted. The filing also includes safety***

> ***and tolerability data for over 1,100 patients administered OLINVO across Phase 2 and Phase 3 studies, including the ATHENA open label safety study. Additional pharmacokinetic data, clinical pharmacology data, and results from five randomized controlled trials with head to head comparisons to morphine, support potential differentiation of OLINVO.***

77. On March 7, 2018, Trevena issued a press release announcing its fourth quarter and fiscal 2018 financial results for the interim period ended December 31, 2017. The press release stated:

> "***2017 marked important progress for Trevena as we completed our Phase 3 program and NDA submission for OLINVO and prepared to support commercial launch***," said Maxine Gowen, Ph.D., chief executive officer. "***We look forward to potential approval of OLINVO later this year***, as well as advancement of our earlier R&D programs. We remain committed to bringing patients innovative medicines for safer and more successful pain management."
>
> **2017 And Recent Corporate Highlights**
>
> - **New Drug Application (NDA) for OLINVO submitted and accepted.** ***In January 2018, the Company announced that the FDA has accepted the Company's NDA for OLINVO***. OLINVO is an investigational product for the management of moderate to severe acute pain. It is the first G protein biased ligand of the mu receptor designed to provide IV opioid pain relief with fewer associated adverse effects. ***The FDA has informed the Company that it intends to convene an advisory committee meeting to discuss the OLINVO NDA ahead of the Prescription Drug User Fee Act (PDUFA) review date of November 2, 2018. If approved, the Company expects commercial launch of OLINVO in the first quarter of 2019 following DEA scheduling.***

78. On March 7, 2018, Trevena filed its Annual Report on Form 10-K with the SEC for the fiscal year ended December 31, 2017 (the "2017 Form 10-K"). The 2017 Form 10-K was signed by defendants Gowen, Moulder, Dougherty, McHugh, Nunn, Phillips, Yanni, Koppel, and Cuca. In the 2017 Form 10-K, these defendants stated the following concerning the Phase III clinical trial and anticipated commercialization of Olinvo:

> *Clinical development*

We are developing OLINVO for the management of moderate-to-severe acute pain where IV administration is preferred. In the future, we also may explore other formulations, such as transmucosal administration for breakthrough pain in additional, separate clinical trials. ***In the second quarter of 2017, we held a successful Type B meeting with the FDA regarding the Chemistry, Manufacturing and Controls data package of our NDA submission for OLINVO. We also held a successful pre-NDA meeting with the FDA regarding the clinical and non-clinical data package of the NDA in the second quarter of 2017.***

Below is a summary of the clinical development work undertaken for OLINVO.

* * *

APOLLO-1 and APOLLO-2 Phase 3 Studies

We have conducted two pivotal efficacy trials evaluating OLINVO in patients with moderate-to-severe acute pain: the APOLLO-1 study, which evaluated pain for 48 hours following bunionectomy, and the APOLLO-2 study, which evaluated pain for 24 hours following abdominoplasty. ***In February 2017, we announced positive top-line results from the APOLLO-1 and APOLLO-2 studies. In both studies, all dose regimens achieved the primary endpoint of statistically greater analgesic efficacy than placebo, as measured by responder rate.***

* * *

Regulatory

In December 2015, the FDA granted Fast Track designation to OLINVO for the management of moderate-to-severe acute pain. The Fast Track program is designed to facilitate the development and review of drugs intended to treat serious conditions with unmet medical needs by providing sponsors with the opportunity for frequent interactions with the FDA. In February 2016, the FDA granted Breakthrough Therapy designation to OLINVO for the management of moderate-to-severe acute pain. Breakthrough Therapy designation is granted by the FDA to new therapies intended to treat serious conditions and for which preliminary clinical evidence indicates that the drug may demonstrate substantial clinical improvement over available therapies. Breakthrough Therapy designation provides all the benefits of the Fast Track program, as well as more intensive FDA guidance on preparing an efficient drug development program. ***In January 2018, we announced that the FDA had accepted for review the NDA we submitted for OLINVO.*** The FDA also indicated that the PDUFA review date for the OLINVO NDA is November 2, 2018 and that it plans to hold an advisory committee meeting to discuss the NDA.

Commercialization

According to 2015 IMS data, approximately 51 million patients in the United States were treated with an IV opioid in the hospital setting. The majority of use is in the inpatient setting where approximately 16 million patients are treated for an average of two days. The World Health Organization estimates that over 230 million major surgical procedures are performed each year worldwide. The Centers for Disease Control and Prevention, or CDC, estimate that 100 million surgical and invasive diagnostic procedures occur annually in the United States. ***Accordingly, if approved, we believe that there is a large potential commercial opportunity for OLINVO in the management of both surgical and medical acute pain.***

If OLINVO ultimately receives regulatory approval, we plan to commercialize it in the United States, either on our own or with a commercial partner. ***Assuming approval on the November 2, 2018 PDUFA review date and allowing for DEA scheduling of OLINVO within 90 days of FDA approval (as mandated by the Improving Regulatory Transparency for New Medicinal Therapies Act), we anticipate launching OLINVO in the first quarter of 2019.*** Outside the United States, we expect to seek collaborators to commercialize OLINVO to offset risk and preserve capital.

79. On May 3, 2018, Trevena issued a press release announcing its first quarter 2018 financial results for the interim period ended March 31, 2018. The press release stated:

"In 2018, we have made important progress in Trevena's evolution," said Maxine Gowen, Ph.D., president and chief executive officer. . . . "***We continue to have an ongoing productive dialogue with the FDA as they review our oliceridine NDA, and look forward to an advisory committee meeting later this year and potential approval in November.***"

First Quarter And Recent Corporate Highlights

- **New Drug Application (NDA) for oliceridine submitted and accepted**. In January 2018, the Company announced that ***the FDA has accepted the Company's NDA for oliceridine***, an investigational product for the management of moderate to severe acute pain. Oliceridine is the first G protein biased ligand of the mu receptor, and was designed to provide IV opioid pain relief with fewer associated adverse effects. ***The FDA has informed the Company that it intends to convene an advisory committee meeting to discuss the oliceridine NDA ahead of the Prescription Drug User Fee Act (PDUFA) review date of November 2, 2018. If approved, the Company expects commercial launch of oliceridine in the first quarter of 2019, following DEA scheduling.***

80. On June 29, 2018, Trevena announced that it had entered into a Sales Agreement with Cowen and Company LLC ("Cowen") pursuant to which it would issue to Cowen and Cowen would sell up to $50 million of Trevena common stock at market prices. Trevena filed a prospectus with the SEC in connection with this anticipated offering that expressly incorporated by reference the Company's 2017 Form 10-K and its first quarter 2018 10-Q, among other filings the Company had made with the SEC. It also expressly incorporated by reference all of the filings Trevena made with the SEC until the offering was complete.

81. On August 2, 2018, Trevena issued a press release announcing its second quarter 2018 financial results for the interim period ended June 30, 2018. The press release stated:

> "The second quarter saw important progress towards Trevena's long-term success," said Maxine Gowen, Ph.D., President and Chief Executive Officer. "***We remain confident that the oliceridine NDA remains on track for an FDA decision by the November 2, 2018 PDUFA date, and we look forward to discussing the oliceridine data at an Advisory Committee meeting, likely in October***. . . ."
>
> **Second Quarter And Recent Corporate Highlights**
>
> - **Prescription Drug User Fee Act (PDUFA) date for oliceridine: November 2, 2018.** Oliceridine is an investigational product under FDA review for the management of moderate to severe acute pain where parenteral opioid analgesia is warranted and was designed to provide the pain relief of IV opioids with fewer associated adverse effects. ***The FDA has informed the Company that it intends to convene an advisory committee meeting, likely in October, to discuss the oliceridine NDA. If oliceridine is approved by the FDA, and following DEA scheduling, the Company expects the commercial launch of oliceridine in the first half of 2019.***

THE FDA REVEALS THE TRUTH CONCERNING THE PHASE III TRIALS

82. As explained above, on October 9, 2018, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee issued a Briefing Document in preparation of the October 11, 2018, meeting to vote on its recommendation to the FDA concerning its approval of Olinvo. The Briefing Document revealed for the first time to the public the various flaws in the

methodology behind the Phase III study and the FDA's constant complaints to Trevena about the study.

83. The market, realizing that Olinvo's rejection was all but assured as a result of the issues addressed in the briefing document, reacted swiftly. The Company's stock price fell nearly $2 per share, closing at $1.07 per share on October 9, 2018, down from its close of $2.98 per share on October 8, 2018, a decline in market capitalization of 64%, or $145 million.

84. As could be expected from the Briefing Document, the Advisory Committee voted against recommending the approval of Olinvo. On November 2, 2018, Trevena announced that it received a Complete Response Letter ("CRL") from the FDA. The FDA's CRL refused to approve Olinvo and requested "additional clinical data on QT prolongation and indicated that the submitted safety database is not of adequate size for the proposed dosing. The FDA also requested certain additional nonclinical data and validation reports."

85. On this news, the Company's stock price fell from $1.05 per share to close at just $0.71 per share, a market capitalization drop of almost $26 million. Between Trevena's relevant period high and the low when the truth reached the market, the Company's stock price fell from $8 per share to just $0.60 per share, a market capitalization loss of almost $370 million, nearly 90%.

REASONS THE STATEMENTS WERE IMPROPER

86. The statements referenced above were each improper when made because they failed to disclose and misrepresented the following material, adverse facts, which the Individual Defendants knew, consciously disregarded, or were reckless in not knowing:

(a) that the Company's Phase III trials of Olinvo was inadequately designed;

(b) the FDA told Trevena that it disagreed with key aspects of the Phase III at multiple meetings about Olinvo's Phase III design and refused to agree to key aspects of the trials;

(c) the FDA did not agree with how the Company compiled safety data for Olinvo; and

(d) as a results of the above, the FDA's rejection of Olinvo based on insufficient support was nearly assured and therefore, Olinvo was not on track to reach the market.

DAMAGES TO TREVENA

87. As a result of the Individual Defendants' improprieties, Trevena disseminated improper, public statements. These improper statements have devastated Trevena's credibility as reflected by the Company's almost $370 million, or nearly 90%, market capitalization loss.

88. Trevena's performance issues also damaged its reputation within the business community and in the capital markets. Trevena's ability to raise equity capital or debt on favorable terms in the future is now impaired. In addition, the Company stands to incur higher marginal costs of capital and debt because the improper statements and misleading projections disseminated by the Individual Defendants have materially increased the perceived risks of investing in and lending money to the Company. This is a significant problem for Trevena as it relies on the equity and debt markets to fund its operations.

89. Further, as a direct and proximate result of the Individual Defendants' actions, Trevena has expended, and will continue to expend, significant sums of money. Such expenditures include, but are not limited to:

(a) costs incurred from defending and paying any settlement in the Securities Class Actions for violations of federal securities laws;

(b) costs incurred from conducting the fundamentally flawed Phase III trials; and

(c) costs incurred from compensation and benefits paid to the defendants who have breached their duties to Trevena.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

90. Plaintiff brings this action derivatively in the right and for the benefit of Trevena to redress injuries suffered, and to be suffered, by Trevena as a direct result of breaches of fiduciary duty, waste of corporate assets, and unjust enrichment, as well as the aiding and abetting thereof, by the Individual Defendants. Trevena is named as a nominal defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.

91. Plaintiff will adequately and fairly represent the interests of Trevena in enforcing and prosecuting its rights.

92. Plaintiff was a stockholder of Trevena at the time of the wrongdoing complained of, has continuously been a stockholder since that time, and is a current Trevena stockholder.

93. The current Board of Trevena consists of the following nine individuals: defendants Bourdow, Gowen, Moulder, Dougherty, McHugh, Nunn, Philips, and Yanni, and nondefendant Scott Braunstein ("Braunstein"). Plaintiff has not made any demand on the present Board to institute this action because such a demand would be a futile, wasteful, and useless act, as set forth below.

DEMAND IS EXCUSED BECAUSE DEFENDANTS BOURDOW, GOWEN, MOULDER, DOUGHERTY, MCHUGH, NUNN, PHILIPS, AND YANNI FACE A SUBSTANTIAL LIKELIHOOD OF LIABILITY FOR THEIR MISCONDUCT

94. As alleged above, defendants Bourdow, Gowen, Moulder, Dougherty, McHugh, Nunn, Philips, and Yanni breached their fiduciary duties of loyalty by making improper statements, including at health conferences, in the Company's press releases, and in SEC filings.

95. Defendants Bourdow, Gowen, Moulder, Dougherty, McHugh, Nunn, Philips, and Yanni breached their fiduciary duty of loyalty to the Company by pushing forward with the Phase III trial despite knowing that the FDA had not signed off on basic aspects of the study, including the endpoints of the study. The Company incurred significant harm by moving forward with the doomed Phase III study. Accordingly, demand on defendants Bourdow, Gowen, Moulder, Dougherty, McHugh, Nunn, Philips, and Yanni is excused.

96. Defendants Dougherty, Koppel, and Yanni, as members of the Audit Committee, reviewed and approved the improper statements and earnings guidance. The Audit Committee's Charter provides that it is responsible for compliance with accounting, legal, and regulatory requirements. The Audit Committee also specifically charges the Audit Committee members with reviewing "earnings press releases, and press releases containing information relating to material developments as well as the substance of financial information, information relating to material developments and earnings guidance provided to analysts and rating agencies." Thus, the Audit Committee Defendants were responsible for knowingly or recklessly allowing the improper statements related to the Company's earnings guidance and financial and disclosure controls. Despite their knowledge or reckless disregard, the Audit Committee Defendants caused these improper statements. Accordingly, the Audit Committee Defendants breached their fiduciary duty of loyalty because they participated in the wrongdoing described herein. Thus, the

Audit Committee Defendants face a substantial likelihood of liability for their breach of fiduciary duties so any demand upon them is futile.

97. The principal professional occupation of defendant Bourdow is her employment with Trevena, pursuant to which she has received and continues to receive substantial monetary compensation and other benefits as alleged above. Accordingly, defendant Bourdow lacks independence from Gowen, Moulder, Dougherty, McHugh, Nunn, Philips, and Yanni due to her interest in maintaining her executive position at Trevena. This lack of independence renders defendant Bourdow incapable of impartially considering a demand to commence and vigorously prosecute this action. Trevena paid defendant Bourdow the following compensation:

Year	Salary	Option Awards	Non-Equity Incentive Plan Compensation	All Other Compensation	Total
2017	$341,169	$606,868	$130,413	$10,800	$1,089,250
2016	$330,417	$520,534	$116,025	$10,600	$977,576

Accordingly, defendant Bourdow is incapable of impartially considering a demand to commence and vigorously prosecute this action because she has an interest in maintaining her principal occupation and the substantial compensation she receives in connection with that occupation. Demand is futile as to defendant Bourdow.

DEMAND IS EXCUSED FOR ADDITIONAL REASONS

98. Nondefendant Braunstein is the operating partner of Aisling Capital. Aisling is an investment firm that invests in products, technologies, and global businesses that advance health. Defendant Dunn is a partner at New Enterprise Associates, Inc. ("New Enterprise"), a venture capital firm that invests in technology and healthcare. Both Aisling and New Enterprise look to invest in new companies in the hopes of a large payoff, and extremely competitive market that is dominated by company founders or long-term employees, such as defendant Gowen. If

defendant Dunn or nondefendant Braunstein voted to initiate litigation against Gowen, they would risk ruining their reputation within the venture capital market and lose opportunities to invest in development stage companies.

99. In addition, defendants Bourdow, Gowen, Moulder, Dougherty, McHugh, Nunn, Philips, and Yanni's previous experience working for companies involved in undergoing clinical trials and working with the FDA to approve new drug products prior to and during their directorship roles at the Company should have alerted them that the Company's Phase III clinical plans had novel endpoints and the structure and plan of the trial did not receive approval from the FDA, which would therefore doom Olinvo's chances for approval. These previous experiences include, but are not limited to:

(a) Defendant Moulder is the founding CEO and member of the Board of Trevena. Prior to Trevena, defendant Moulder served as Vice Chairman of the board of directors, President and CEO of Abraxis BioScience, Inc., a biotechnology company. Before that, defendant Moulder served as Vice Chairman of Eisai Corporation of North America, a pharmaceutical company and wholly owned subsidiary of Eisai Co., Ltd., from January 2008 until January 2009, following Eisai Co., Ltd.'s acquisition of MGI PHARMA, Inc., a pharmaceutical company in January 2008. Defendant Moulder served as President and CEO and as a member of the board of directors of MGI PHARMA, Inc. from May 2003 to January 2008.

(b) Defendant Dougherty was Executive Chairman of Celator Pharmaceuticals, Inc., from August 2015 until July 2016; he also served as a director of Celator from July 2013. Previously, defendant Dougherty was CEO and a member of the board of directors of Kalidex Pharmaceuticals, Inc., from May 2012 to October 2012. Defendant Dougherty was the President and CEO and a director of Adolor Corporation, a

biopharmaceutical company, from December 2006 until December 2011. Defendant Dougherty joined Adolor as Senior Vice President of Commercial Operations in November 2002, and until his appointment as President and CEO in December 2006, served in a number of capacities, including Chief Operating Officer and Chief Financial Officer. From November 2000 to November 2002, defendant Dougherty was President and Chief Operating Officer of Genomics Collaborative, Inc. Previously, defendant Dougherty served in a variety of senior positions at Genaera Corporation, a biotechnology company, including President and CEO, and at Centocor, Inc.

(c) Defendant McHugh was Chief Operating Officer of Endo Health Solutions Inc., a global specialty healthcare company, from March 2010 to May 2013, and since May 2013 she has provided consulting services to companies in the pharmaceuticals industry. Prior to that, from September 2008 to September 2009, she served as CEO of Nora Therapeutics, Inc., a private biotechnology company. From 2006 to 2008 she was Company Group Chairman for Johnson & Johnson's worldwide virology business unit and from 2004 to 2006 she was President of Centocor, Inc., a Johnson & Johnson subsidiary.

(d) Defendant Phillips currently is Senior Vice President of Clinical, Medical and Regulatory Affairs at Novo Nordisk Inc., a pharmaceutical company, where she has served since 2011. Previously, she served as a Vice President in various positions at GlaxoSmithKline plc, which she joined in 1998.

(e) Defendant Yanni was Vice President and Chief Licensing Officer at Merck & Co., a pharmaceutical company, from November 2001 until her retirement in March 2014. Prior to this, defendant Yanni served in various roles at Merck including in corporate

development, financial evaluation, and tax. Defendant Yanni currently serves on the Board of Directors of Symic Holdings, LLC and Vaccinex, Inc., both private biotechnology companies.

100. Plaintiff has not made any demand on the other stockholders of Trevena to institute this action since such demand would be a futile and useless act for at least the following reasons:

(a) Trevena is a publicly held company with over eighty-two million shares outstanding and thousands of stockholders as of November 2, 2018;

(b) making demand on such a number of stockholders would be impossible for plaintiff who has no way of finding out the names, addresses, or phone numbers of stockholders; and

(c) making demand on all stockholders would force plaintiff to incur excessive expenses, assuming all stockholders could be individually identified.

COUNT I

AGAINST THE INDIVIDUAL DEFENDANTS FOR BREACH OF FIDUCIARY DUTY

101. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

102. The Individual Defendants owed and owe Trevena fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe Trevena the highest obligation of good faith, fair dealing, loyalty, and due care.

103. The Individual Defendants and each of them, violated and breached their fiduciary duties of candor, good faith, and loyalty. More specifically, the Individual Defendants violated their duty of good faith by creating a culture of lawlessness within Trevena, and/or consciously failing to prevent the Company from engaging in the unlawful acts complained of herein.

104. The Officer Defendants either knew, were reckless, or were grossly negligent in participating or disregarding the illegal activity of such substantial magnitude and duration. Accordingly, the Officer Defendants breached their duty of care and loyalty to the Company.

105. The Director Defendants, as directors of the Company, owed Trevena the highest duty of loyalty. These defendants breached their duty of loyalty by recklessly participating in or permitting the improper activity detailed herein. Accordingly, these defendants breached their duty of loyalty to the Company.

106. The Audit Committee Defendants breached their fiduciary duty of loyalty by approving the statements described herein which were made during their tenure on the Audit Committee, which they knew or were reckless in not knowing contained improper statements and omissions. The Audit Committee Defendants completely and utterly failed in their duty of oversight, and failed in their duty to appropriately review financial results, as required by the Audit Committee Charter in effect at the time.

107. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Trevena has sustained significant damages, as alleged herein. As a result of the misconduct alleged herein, these defendants are liable to the Company.

108. Plaintiff, on behalf of Trevena, has no adequate remedy at law.

COUNT II

AGAINST THE INDIVIDUAL DEFENDANTS FOR WASTE OF CORPORATE ASSETS

109. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

110. As a result of the wrongdoing described above, including by failing to conduct proper supervision, the Individual Defendants have caused Trevena to waste its assets by paying

improper compensation and bonuses to certain of its executive officers and directors that breached their fiduciary duty, as well as conduct a doomed to fail Phase III trial.

111. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.

112. Plaintiff, on behalf of Trevena, has no adequate remedy at law.

COUNT III
AGAINST THE INDIVIDUAL DEFENDANTS FOR UNJUST ENRICHMENT

113. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

114. By their wrongful acts and omissions, the Individual Defendants were unjustly enriched at the expense of and to the detriment of Trevena. The Individual Defendants were unjustly enriched as a result of the compensation and director remuneration they received while breaching fiduciary duties owed to Trevena.

115. Plaintiff, as a stockholder and representative of Trevena, seeks restitution from these defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits, and other compensation obtained by these defendants, and each of them, from their wrongful conduct and fiduciary breaches.

116. Plaintiff, on behalf of Trevena, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, on behalf of Trevena, demands judgment as follows:

A. Against all of the defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the defendants' breaches of fiduciary duties, waste of corporate assets, and unjust enrichment;

B. Directing Trevena to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect Trevena and its stockholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for stockholder vote, resolutions for amendments to the Company's Bylaws or Articles of Incorporation and taking such other action as may be necessary to place before stockholders for a vote of the following corporate governance policies:

1. a proposal to strengthen the Board's oversight of the Company's interactions with the FDA;

2. a proposal to strengthen the Board's oversight of its disclosure procedures;

3. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater stockholder input into the policies and guidelines of the Board; and

4. a provision to permit the stockholders of Trevena to nominate at least three candidates for election to the Board;

C. Extraordinary equitable and/or injunctive relief as permitted by law, equity, and state statutory provisions sued hereunder, including attaching, impounding, imposing a constructive trust on, or otherwise restricting the proceeds of defendants' trading activities or their other assets so as to assure that plaintiff on behalf of Trevena has an effective remedy;

D. Awarding to Trevena restitution from defendants, and each of them, and ordering disgorgement of all profits, benefits, and other compensation obtained by the defendants;

E. Awarding to plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

F. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: December 20, 2018

Respectfully submitted,

HYNES KELLER & HERNANDEZ, LLC

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Attorneys for Plaintiff

VERIFICATION

I, Hans Mathisen, hereby declare as follows:

I am the plaintiff in the within entitled action. I have read the Verified Stockholder Derivative Complaint for Breach of Fiduciary Duty, Waste of Corporate Assets, and Unjust Enrichment. Based upon discussions with and reliance upon my counsel, and as to those facts of which I have personal knowledge, the Complaint is true and correct to the best of my knowledge, information, and belief.

I declare under penalty of perjury that the foregoing is true and correct.
Signed and Accepted:

Dated: Dec. 18, 2018

H. H. Mathisen

Hans Mathisen